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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Group Art Unit: 1615

Confirmation No.: 2101

Examiner: Amy E. Pulliam

Filed: December 21, 1999

For:

PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed after either a Final Office

Action, Notice of Allowance, or an action that otherwise closes prosecution in the application

(whichever is earlier), but before payment of the Issue Fee, and therefore Applicant is submitting

Q57234

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 09/446,276

herewith a check for the fee of \$180.00 under 37 C.F.R. § 1.17(p), and a Statement Under 37 C.F.R. § 1.97(e).

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

Registration No. 40,641

SUGHRUE MION, PLLC '

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

> WASHINGTON OFFICE 23373 CUSTOMER NUMBER

Date: December 30, 2004

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 09/446,276

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overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: December 30, 2004

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Group Art Unit: 1615

Confirmation No.: 2101

Examiner: Amy E. Pulliam

Filed: December 21, 1999

For: PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA

STATEMENT UNDER 37 C.F.R. § 1.97(e)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The undersigned hereby states, upon information and belief:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

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washington office 23373 customer number

Date: December 30, 2004

ennifer M. Hayes

Registration No. 40,641

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Substitute for Form 1449 A & B/PTO DEC 3 0 2004		Complete if Known		
Substitute for Form	1477441110	<u> </u>	Application Number	09/446,276
INF	ORMATIOÑ.	DISCLOSURE	Confirmation Number	2101
STATEMENT BY APPLICANT			Filing Date	December 21, 1999
2			First Named Inventor	Yoshihisa NISHIBE
(use as many sheet	s as necessary)	Art Unit	1615
			Examiner Name	Amy E. Pulliam
Sheet	1	of 1	Attorney Docket Number	O57234

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number		Publication Date	
		Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US 5,188,826		02-23-1993	Chandrasekaran et al.
		US 5,192,535		03-09-1993	Davis et al.
		US 5,474,768		12-12-1995	Robinson
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		US 4,615,697		10-07-1986	Robinson
		US 4,271,143		06-02-1981	Schoenwald et al.
		US			·
		US			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite	Foreign Patent Document		Publication Date	Name of Patentee or		
		No.1	Country Code ³	Number⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document
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NON PATENT LITERATURE DOCUMENTS					
Examiner Cite Initials* No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.			

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Evaminas Cianatura		Date Considered	
Examiner Signature	•	Date Considered	
			

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.